श्री राम विलास पासवान: ठीक है।

एक माननीय सदस्य: सभापति जी।

श्री सभापति: आपका नाम है इसमें।

Functioning of Drugs Control Organizations

*147. PROF. ALKA BALRAM KSHATRIYA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that sub-standard medicines in the country are being sold and the Drug Controller has failed to curb their sale;

(b) if so, the reasons therefor;

(c) whether Dr. Mashelkar Committee Report has pointed out the inadequacy in the Drugs Control Organisations (DCOs) at the Central and State level and has recommended the strengthening of DCOs; and

(d) if so, what steps Government have taken in this regard?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS): (a) to (d) A Statement is laid on the Table of the House.

Statement

Under the provisions of Drugs and Cosmetics Act, 1940, and Rules framed thereunder, the State Governments, through their respective Drugs Control Organizations, are empowered to regulate manufacture of drugs and to monitor the quality of drugs moving in the inter-State commerce.

There are a number of quality standards prescribed for drugs in the Drugs and Cosmetics Act. Deviation in any of the parameters of the overall standards laid down, may result in a drug being declared as "not of standard quality" or "sub-standard". Any drug found not of standard quality/ substandard is withdrawn from the market by the concerned State Drug Control Authorities and cannot be sold.

Sub-standard drugs can result due to inadequate pre-formulation development, lack of in-process controls exercised by the manufacturer, improper conditions under which drugs are stored and transported in the supply chain etc.

Another distinct category is of "Spurious Drug". As per Section 17-B of the Drugs and Cosmetics Act, 1940, a drug shall be deemed to be spurious if it is manufactured under a name which belongs to another drug, if it is an imitation of another drug or if it has been substituted wholly or partly by another drug or if it wrongly claims to be the product of another manufacture.

As per the feedback available from the Drugs Controllers of States/ UTs, 38824, 36314 and 39465 samples were tested during the period 2001-02, 2002-03 and 2003-04, out of which 3458, 3395 and 3441 samples were declared to be not of standard quality (*i.e.* 8.9 percent, 9.34 percent and 8.72 percent respectively of the samples tested) and 96, 125 and 108 samples respectively were found spurious (i.e.0.25 percent, 0.34 percent and 0.27 percent of the samples tested).

Government of India had constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelkar to examine all the aspects regarding the drug regulatory infrastructure and the extent and the problem of spurious/sub-standard drugs in the country. The main observations of the said Committee in respect of strengthening of Drugs Control Organizations at the Central and State level are as follows:-

(i) The problems in the regulatory systems in the country were primarily due to inadequate or weak drug control infrastructure at the State and Central level, inadequate testing facilities, shortage of drug inspectors, non-uniformity of enforcement, lack of specially trained cadres for specific regulatory areas, non-existence of data bank and non-availability of accurate information.

(ii) The existing infrastructure at the Centre and States is inadequate to perform the assigned functions, therefore, it is essential to strengthen the existing organizations.

(iii) A well equipped and professionally managed CDSCO, which could be given the status of Central Drugs Administration (CDA) was the most appropriate solution.

Measures taken by the Government are:

(1) The Mashelkar Committee Report has been circulated to all the State Governments for their comments on the implementation of the measures recommended by the Committee.

(2) A World Bank assisted Capacity Building Project on Food Safety and Quality Control of Drugs has been launched *w.e.f.* October, 2003. The project aims at strengthening, *inter alia*, the Drug Regulatory infrastructure in the country by augmenting the drug testing facilities by providing for equipments, civil works, staff and consumables and extensive training of drug regulatory/quality control officials and industry personnel. The interventions proposed under this project, once completed, would, it is hoped, lead to an increase in the number of samples tested in the country from 36,000 per year to one lakh per year and would substantially reduce the reporting time by Government testing labs. In order to improve the competence and efficiency of State Drug Control Officers, comprehensive training programmes on investigational skills, Good Manufacturing Practices (GMP) auditing, concept of Good Laboratory Practices (GLP), Product Development etc. are being conducted.

प्रो. अलका क्षत्रिय: सभापति जी, नकली और घटिया दवाई बेचने वाले लोगों की जिंदगी के साथ खिलवाड़ करते हैं, जिससे कभी-कभी मरीज की मौत भी हो जाती है। इसके सबसे ज्यादा शिकार गरीब मरीज होते हैं। मैं माननीय मंत्री जी से जानना चाहती हूं कि ऐसी नकली और घटिया दवाइयां बेचने वाले लोगों के खिलाफ आपने क्या कदम उठाए हैं? साथ ही साथ मैं मंत्री जी से गुजारिश भी करती हूं कि ऐसी नकली और घटिया दवाइयां बेचने वाले लोगों के खिलाफ कड़ी से कड़ी कार्रवाई हो जाए, इसके लिए भी प्रावधान किया जाए।

DR. ANBUMANI RAMADOSS: Sir, we are monitoring the situation in the country regarding sub-standard drugs as well as spurious drugs. There are two categories in this. One is sub-standard or low-quality drugs and the other is spurious drugs. A Bill was introduced in the last session of Parliament for amending the Drugs and Cosmetics Act to make more stringent laws to curb this menace. But, it lapsed. Another Bill pertaining to the same amendment of the Drugs and Cosmetics Act is there. It was put up before the Cabinet and the Cabinet wanted some modifications in that. it has now gone to the Law Ministry and once it comes out, Sir, we will introduce this Bill in the Parliament whereby a lot more stringent measures are contemplated to prevent the sale and manufacture of sub-standard as well as spurious drugs. Sir, this is again both a Centre as well as a State issue. We make the policies. We give money for infrastructure building at the State level. The State Drug Control Authority is the authority which has the

monitoring capacity and it is the duty of this Authority to monitor all the manufacturers as well as the sales of these drugs in the market. We have gone for a capacity-building process. It is a World Bank aided project whereby we are spending about Rs. 356.25 crores, out of which Rs. 214.52 crores are going for the food capacity building and, for the drugs, we are spending Rs. 110.85 crores. It is a five-year project. This is capacity building to increase and modernise all the labs in the country for drug testing labs and food testing labs, as well as professional training. All the States are involved and all the States as well as Central labs are going to be modernised to check this problem. Sir, today, there are about only 35,000 to 40,000 samples that are tested every year. It is not enough. So, once we go through this capacity building process, we expect more than hundred thousand samples a year to be tested all around the country to prevent the sale of spurious medicines.

प्रो. अलका क्षत्रिय: सभापति जी, मंत्री जी ने जो कुछ कहा, वह तो उन्होंने अपने जवाब में लिखा है, मैंने उनसे सीधा-सीधा यह सवाल किया था कि आपने अभी तक जो परीक्षण किया और उसमें जितने भी नकली दवाइयां बेचने वाले पाए गए, उनके खिलाफ आपने क्या कार्रवाई की है? दूसरी बात मैं यह पूछना चाहती हूं कि माशेलकर समिति ने जो अपनी रिपोर्ट दी है, जिसे आपने राज्यों को टिप्पणियां लेने के लिए भेज दिया है, लेकिन वे टिप्पणियां कब तक आएंगी और आप इसे कब तक लागू कर रहे हैं, इसका सीधा-सीधा जवाब दें, बाकी सब मैंने उनके जवाब में पढ़ लिया है।

DR. ANBUMANI RAMADOSS: Sir, I understand the concern of the hon. Member as well as of the Members in this House. We are also very much concerned about this issue. Sir, regarding the legal implications and the penal implications, the Drugs and Cosmetics Act was amended in 1982 whereby certain provisions regarding imprisonment as well as fine were amended, and, which were very minimal, so to say, about three to five years of imprisonment, and, only Rupees Ten Thousand of fine in case the drug was found to be a sub-standard or spurious drug. And, if someone is caught for causing a grievous injury or death, then there is a provision for life imprisonment. But, Sir, till today, there is not even one case booked for life imprisonment. This again is a serious issue. We are taking up the issue of amendments to the Drugs and Cosmetics Act, which has been put up before the Cabinet, and, on which my predecessor has also taken very active interest. We will be taking a lot more stringent measures. As far as the issue of financial penalty and the legal penalty is concerned, we are taking a look at it also.

Sir, as far as the Mashelkar Committee's recommendations are concerned, I would submit that this Committee, formed in January, 2003 under the Chairmanship of Dr. Mashelkar to look into all these issues, gave its recommendations in December, 2003. We have sent those recommendations to all the States for their views, and, till today nine States have given their views on the recommendations. The Government also is going into the recommendations like capacity building, training, and all other professional activities, and, we are going to examine these recommendations.

SHRI DINESH TRIVEDI: Sir, I think from the answer given by the Minister, one thing has been proved that the drug control organisation has miserably failed. Sir, I would like to remind the hon. Minister that in the early 1990s, the Government had a policy which says, 'Health for all by 2000'. Sir, we are approaching 2005, and, I would just like to ask a very simple question. My question is: what has happened to that policy?

DR. ANBUMANI RAMADOSS: Sir, even though this does not relate to the main question..(*Interruptions*)..

SHRI DINESH TRIVEDI: Sir, it is related...(*Interruptions*).. After all, it is health. It definitely relates to the question.

DR. ANBUMANI RAMADOSS: Sir, the Government is definitely concerned about 'Health for All'. We have the National Health Policy, which we are going through, and, specially the rural health, which is a big concern. Sir, regarding the first part of your question that not much has been done by the drug authorities in the country, I am with you.

SHRI DINESH TRIVEDI: Sir, you cannot let the people die because of lack of your infrastructure.

DR. ANBUMANI RAMADOSS: Sir, the drug monitoring is a serious issue..(*Interruptions*)..

SHRI DINESH TRIVEDI: Sir, it is a very serious issue, and, the..(*Interruptions*)..

DR. ANBUMANI RAMADOSS: Sir, this is a very serious issue that we are confronting with, and, today the Government is fully committed to improve the drug monitoring capacity in the country, and, in the days to come, in January, we are going in for the Product Patent Act, and, in the

country there are lot more R&D projects coming out. Sir, we have to compete with the rest of the world, and, we are going to improve..(*Interruptions*)..

डा॰ मुरली मनोहर जोशी: सर, अभी मंत्री जी ने कहा था कि वे कम्पलसरी लाइसेंसिंग की व्यवस्था रखेंगे, तो क्या इस प्रोडक्ट पर पेटेन्ट रिजीम के अन्तर्गत वह रहेगी?

DR. ANBUMANI RAMADOSS: Sir, we are totally committed towards...(*Interruptions*)...

SHRI DINESH TRIVEDI: Are you carrying on the policy of 'Health for All'?

DR. ANBUMANI RAMADASS: Sir, we are doing a lot of processes through which the drugs monitoring mechanism is going to be strengthened in the country, and, made more competent with the rest of the world. We are moving towards that. I am committing this before the House that we are towards achieving that goal.

MR. CHAIRMAN: Question Hour is over.

WRITTEN ANSWERS TO STARRED QUESTIONS

Pollution by thermal power plants

†*142. SHRI ABU ASIM AZMI: Will the Minister of ENVIRONMENT AND FORESTS be pleased to state:

(a) the total quantum of fly-ash produced in each thermal power plant through the waste products released from these plants annually in the country;

(b) whether any measures have been taken by Government for checking pollutants releasing from the thermal power plants;

(c) if so, the details thereof; and

(d) the total amount being spent annually by Government for the same?

THE MINISTER OF ENVIRONMENT AND FORESTS (SHRI A. RAJA): (a) The total quantum of fly-ash generated in 2003-04 in 120 thermal

†Original notice of the question was received in Hindi.